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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,983	10/31/2001	Hans Josef Stauss	ICI 103	6029

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PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE
SUITE 1200
ATLANTA, GA 30361

EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/003,983	STAUSS ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7, drawn to a peptide comprising an HLA-binding peptide of human CD45 polypeptide or a portion or variant thereof and/or fusion protein thereof with HLA heavy chain and flexible linker, classified in Class 530, subclasses 328 and 402.

II. Claims 8-12, drawn to nucleic acids encoding ligand that is a peptide comprising an HLA-binding peptide of human CD45 polypeptide or a portion or variant thereof and/or fusion protein thereof with HLA heavy chain and flexible linker, vectors, transformants and expression thereof, classified in Class 536, subclasses 23.5, Class 435, subclasses 69.1, 70.1, 252.3, 320.1.

III. Claims 13-18, drawn to an APC loaded with a peptide and a kit comprising a peptide and an APC, classified in Class 424, subclasses 93.7 and 185.1, and Class 435, subclass 975, respectively.

IV. Claims 19, 21 and 23, drawn to a method for producing activated CTL in vitro, comprising contacting syngeneic CTL with syngeneic APC loaded with peptides, classified in Class 435 subclass 325.

V. Claims 19 and 22, drawn to a method for producing activated CTL in vitro, comprising contacting syngeneic CTL with syngeneic APC that comprise an expression vector which expresses a peptide, classified in Class 435 subclass 252.3.

VI. Claims 19 and 20, drawn to a method for producing activated CTL in vitro, comprising contacting allogeneic CTL with allogeneic APC and peptide, classified in Class 435, subclass 377.

VII. Claims 24-26, drawn to activated CTL, classified in Class 424, subclass 93.71.

VIII. Claims 27 and 28, drawn to a TCR or a functionally equivalent molecule that recognizes a malignant haematopoietic cell that expresses CD45, classified in Class 530, subclass 350.

IX. Claims 29 and 30, drawn to a polynucleotide and expression vector thereof, encoding a TCR that recognizes a cell that expresses a polypeptide comprising the amino acid sequence of Claim 1 or a TCR or functional equivalent that recognizes a malignant haematopoietic cell that expresses CD45.

X. Claims 31-34, drawn to a method of killing target cells in a patient, comprising administering activated CTL, classified in Class 424, subclass 93.7.

XI. Claims 35-38, drawn to a method of treating a patient with a haematopoietic malignancy, classified in Class 435, subclass 7.2 and Class 424, subclass 93.71.

XII. Claim 39, drawn to a library of activated CTL, classified in Class 435, DIG.26.

XIII. Claim 40, drawn to a library of HLA-binding peptides of human CD45 polypeptide, classified in Class 435, DIG.22.

XIV. Claim 41, drawn to a library of APC loaded with an HLA-binding peptide of human CD45 polypeptide, classified in Class 435, DIG.26.

2. Inventions II and Invention V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

3. Inventions III and Invention IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

4. Inventions II and Invention V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

5. Inventions III and Invention VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

6. Inventions VII and Invention X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

7. Inventions XII and Invention X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

8. Inventions IV, V, VI, X and XI are different methods.

These inventions require different ingredients and process steps to accomplish the use of producing activated CTL in vitro (Inventions IV, V and VI) or of killing target cells in a patient (Invention X) or of treating a patient with a haematopoietic malignancy (Invention XI). For example, the method of Invention IV uses syngeneic CTL and syngeneic APC loaded with peptides, whereas the method of Invention V uses syngeneic CTL and syngeneic APC that are transfected with expression vector that expresses a peptide, whereas the method of Invention VI uses allogeneic CTL and APC. The method of Invention X administers peptide specific CTL whereas the method of Invention XI administers allogeneic CTL after stem cell transplantation.

9. Inventions I-III, VII, VIII, IX and XII-XIV are different products.

A protein or peptide (Inventions I, XII) is different from a nucleic acid molecule (Invention II) or a cell (Inventions VII, XII, XIV). Proteins are comprised of amino acid residues, whereas nucleic acid molecules are comprises of nucleotide bases and saccharides and cells are compositions comprising organelles and substructures. The peptide of Invention I is different from the protein of Invention VIII because it is a TCR protein with a different structure and function. The nucleic acid molecule of Invention II is different from the polynucleotide of Invention IX because that polynucleotide encodes a TCR protein with a different structure and function. The library of HLA-binding peptides of Invention XIII is different from the product of Invention I because the library is a composition of many different peptides that bind to many different HLA molecules. The library of Invention XII is comprised of a collection of activated CTL specific for different peptides/HLA specificities, whereas the library of Invention XIV is a collection of APC, a different cell type, that express HLA molecules in conjunction with antigenic peptides. The kit of Invention III is different from the other products because it comprises a peptide and an APC separately.

Therefore they are patentably distinct.

10. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-XIV is not required for any other group from Groups I-XIV and Groups I-XIV have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended

during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. **If Applicant elects the Invention of Group I**, Applicant is further required to (1) elect a single disclosed species (a ***specific peptide containing either only peptide bonds or including non-peptide bonds***, for example, one comprising SEQ ID NO: 1-3 that only contains peptide bonds, *or* a ***specific single chain peptide/HLA molecule***, for example, /SEQ ID NO: 3/HLA-A0201) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

13. **If Applicant elects the Invention of Group II**, Applicant is further required to (1) elect a single disclosed species of polynucleotide/vector/host cell/method of production encoding a specific peptide (a ***specific peptide containing either only peptide bonds or including non-peptide bonds***, for example, one comprising SEQ ID NO: 1-3 that only contains peptide bonds or a ***specific single chain peptide/HLA molecule***, for example, /SEQ ID NO: 3/HLA-A0201) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

14. **If Applicant elects the Invention of Group III**, Applicant is further required to (1) elect a single disclosed species of peptide and an APC expressing a specific MHC molecule to which the peptide binds as well as a specific species of APC (a ***specific peptide and a specific HLA molecule and a specific APC***, for example, SEQ ID NO: 3 and HLA-A0201 and T2 APC) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

15. **If Applicant elects the Invention of Group IV**, Applicant is further required to (1) elect for use in the claimed method, a single disclosed species of APC expressing a specific MHC molecule to which a specific peptide binds (a ***specific peptide and a specific HLA molecule and a specific APC***, for example, SEQ ID NO: 3 and HLA-A0201 and T2 APC) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

16. **If Applicant elects the Invention of Group V**, Applicant is further required to (1) elect for use in the claimed method, a single disclosed species of APC expressing a specific MHC molecule to which a specific peptide binds, said peptide being expressed in a specific expression vector (a ***specific peptide and a specific HLA molecule and a specific APC***, for example, SEQ ID NO: 3 and HLA-A0201 and T2 APC) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

17. **If Applicant elects the Invention of Group VI**, Applicant is further required to (1) elect for use in the claimed method, a single disclosed species of APC expressing a specific MHC molecule to which a specific peptide binds (a ***specific peptide and a specific HLA molecule and a specific APC***, for example, SEQ ID NO: 3 and HLA-A0201 and T2 APC) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.
These species are distinct because their structures are different.

18. **If Applicant elects the Invention of Group VII**, Applicant is further required to (1) elect a single disclosed species CTL that recognize a specific MHC/peptide combination (a ***specific peptide and a specific HLA molecule***, for example, SEQ ID NO: 3 and HLA-A0201) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

19. **If Applicant elects the Invention of Group VIII**, Applicant is further required to (1) elect a single disclosed species of TCR or a specific species of functionally equivalent molecule that recognizes a specific MHC/peptide combination (a ***specific peptide and a specific HLA molecule***, for example, SEQ ID NO: 3 and HLA-A0201) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

20. **If Applicant elects the Invention of Group IX**, Applicant is further required to (1) elect a single disclosed species of polynucleotide that encodes a specific TCR or a specific species of functionally equivalent molecule that recognizes a specific MHC/peptide combination (a ***specific peptide and a specific HLA molecule***, for example, SEQ ID NO: 3 and HLA-A0201) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

21. **If Applicant elects the Invention of Group X**, Applicant is further required to (1) elect for use in the claimed method, a single disclosed species of peptide expressed on target cells of the patient, a specific disclosed species of CTL that recognizes a specific MHC/peptide combination (a ***specific peptide and a specific HLA molecule***, for example, a peptide containing SEQ ID NO: 1-3 and a CTL that recognizes SEQ ID NO: 3 and HLA-A0201) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

22. **If Applicant elects the Invention of Group XI**, Applicant is further required to (1) elect for use in the claimed method, a single disclosed species of peptide expressed on target cells of the patient, a specific disclosed species of CTL that recognizes a specific MHC/peptide combination (a ***specific peptide and a specific HLA molecule***, for example, a peptide containing SEQ ID NO: 1-3 and a CTL that recognizes SEQ ID NO: 3 and HLA-A0201) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

23. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

24. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

25. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

26. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

27. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

28. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
September 24, 2004

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600